

## **REMARKS**

### **1. STATUS OF THE CLAIMS**

Claims 1-19 were originally filed. Claims 1-6 and 15-19 were previously withdrawn as being directed to a non-elected invention. Claims 7-14 are pending.

Claim 7 is currently amended to recite "determining the level of specific binding."

Support is in the Specification at, for example,

"The invention's methods involve detecting the level of specific binding of the isolated nucleotide sequence with RelB RHD, as exemplified by SEQ ID NO:62. Methods for "detecting" such binding are known in the art and disclosed herein. For example, binding of polypeptides (including dimerized polypeptides such as RelB:p52 and RelA:p50) to DNA molecules may be **determined** by methods including, but are not limited to, direct binding in solution, direct binding where one or more components is immobilized on a solid surface, electrophoretic mobility shift assays, nucleolytic cleavage protection assays such as DNase I footprinting assay, reporter gene assay, optical affinity biosensor system assay, PCR-based target detection assay, chemical footprinting assay, filter binding assay, immunological assay, sedimentation centrifugation assay, spectroscopic assay, HPLC and other column and thin layer chromatographic assays, immunologic detection assays such as ELISA, tagged antibody, and precipitation assays. These exemplary methods are disclosed in the art such as in U.S. Patent Nos. 5,783,384, 6,333,153."<sup>1</sup>

"The level of specific binding of the isolated nucleotide sequence that contains the invention's RelB $\kappa$ B sequences (*e.g.*, SEQ ID NO:57) with the protein RelB RHD, as exemplified by SEQ ID NO:62, may be **determined** using an "array", *i.e.*, a plurality (*i.e.*, more than one) of reaction compartments. In one embodiment, each of the reaction compartments comprises one test compound."<sup>2</sup>

Claim amendments were made to describe particular embodiments of the invention,

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<sup>1</sup> (Emphasis added) Specification, paragraph bridging pages 49-50.

<sup>2</sup> (Emphasis added) Specification, page 50, lines 14-18.

notwithstanding Applicants' belief that the un-amended claims would have been allowable, without acquiescing to any of the Examiner's arguments, and without waiving the right to prosecute the un-amended (or similar) claims in another application, but rather for the purpose of furthering Applicants' business goals and expediting the patent application process in a manner consistent with the PTO's Patent Business Goals (PBG).<sup>3</sup>

2. **REJECTION OF CLAIMS 7, 8, 10, 11, 13 AND 14 UNDER 35 U.S.C. §102(b) OVER SACCANI *et al.***

The Examiner rejected Claims 7, 8, 10, 11, 13 and 14 under 35 U.S.C. §102(b) for alleged anticipation by Saccani *et al.* (Molecular Cell, 2003 11:1563-1574).<sup>4</sup> Applicants respectfully traverse because Saccani *et al.* is not prior art under either 35 U.S.C. §102(b) or §102(a), as further discussed below.

**A) Saccani *et al.* is not prior art under 35 U.S.C. §102(b)**

The Examiner is respectfully reminded that under 35 U.S.C. § 102(b):

“A person shall be entitled to a patent unless ... the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States.”

The instant application claims priority to U.S. provisional application Ser. No. 60/508,349, filed on October 1, 2003. Saccani *et al.* was published on July 3, 2003 as shown by the date stamp on the cover of the issue of Molecular Cell, volume 11 Number 6 (Tab 1), in which Saccani *et al.* was disclosed. Since Saccani *et al.*'s publication date of July 3, 2003 is **not** “more than one year prior to” the October 1, 2003 priority date, Saccani *et al.* is not prior art under 35 U.S.C. § 102(b). Therefore, Applicants respectfully request withdrawal of the rejection of Claims 7, 8, 10, 11, 13 and 14 under 35 U.S.C. §102(b) for alleged

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<sup>3</sup> 65 Fed. Reg. 54603 (September 8, 2000).

<sup>4</sup> Office Action, page 2, last full paragraph.

anticipation by Saccani *et al.*

**B) Saccani *et al.* is not prior art under 35 U.S.C. §102(a)**

While the Examiner did not reject the claims under 35 U.S.C. §102(a) for alleged anticipation by Saccani *et al.*, Applicants nonetheless address this potential rejection in view of the above finding regarding the publication date of Saccani *et al.* Under 35 U.S.C. § 102(a):

“A person shall be entitled to a patent unless (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent.”

Priority of invention may be demonstrated by a declaration under 37 C.F.R. §1.131 in order “to establish invention of the subject matter of the rejected claim prior to the effective date of the reference or activity on which the rejection is based.”<sup>5</sup>

The enclosed Declaration by Dr. Karin as supported by its Exhibit A, explain that, “prior to July 3, 2003,” the co-inventors completed experiments in which they demonstrated the “previously unknown” specificity<sup>6</sup> of sequences of different  $\kappa$ B sites that are encompassed by the claims’ recited 5’-NGGAGANNTG-3’ (SEQ ID NO:57).<sup>7</sup> The Declaration further describes competition experiments in which DNA sequences containing the claims’ recited 5’-NGGAGANNTG-3’ (SEQ ID NO:57) were contacted with polypeptide sequence RelB:p52 that contains the claims’ recited Rel homology domain listed as SEQ ID NO:62.<sup>8</sup> This contacting was performed in the presence and absence of competitive sequences (i.e., sequences encompassed by the claims’ recited “test compounds”), and was followed by determining the level of binding of the DNA sequences with the polypeptide sequences.<sup>9</sup>

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<sup>5</sup> 37 C.F.R. §1.131; MPEP §715

<sup>6</sup> Dr. Karin’s Declaration, paragraph 8.

<sup>7</sup> Dr. Karin’s Declaration, paragraph 7, referring to the exemplary sequences GGGACTTTCC, GGGAGATTTC, AGGAGATTTC, and GGGATTCCCC.

<sup>8</sup> Dr. Karin’s Declaration, paragraph 8.

<sup>9</sup> *Id.*

In view of the above, the co-inventors invented the subject matter of the claims **prior** to the July 3, 2003 publication date of Saccani *et al.* Thus, Saccani *et al.* is **not** prior art under 35 U.S.C. §102(a).

3. **REJECTION OF CLAIM 12 UNDER 35 U.S.C. §103(a) OVER SACCANI *et al.* IN VIEW OF TOLEDANO *et al.***

The Examiner rejected Claim 12 under 35 U.S.C. §103(a) for allegedly being obvious over Saccani *et al.* in view of Toledano *et al.* (PNAS, 1991 88:4328-4332).<sup>10</sup> Applicants respectfully traverse because the primary reference Saccani *et al.* is not prior art under 35 U.S.C. §103(a).

The Examiner is respectfully reminded that to be prior art under 35 U.S.C. §103, a reference must first qualify as prior art under 35 U.S.C. §102(a), (b), (e), (f), or (g).<sup>11</sup> However, as discussed above, Saccani *et al.* is not prior art under either §102(a) or §102(b).

In addition, Saccani *et al.* also is not prior art under §102(e) because it is not a patent or patent application. Moreover, Saccani *et al.* is not prior art under either §102(f) or §102(g) because there are no facts supporting either derivation under §102(f) or interference under §102 (g).

Since Saccani *et al.* is not prior art under any one of §102(a), (b), (e), (f), or (g), it cannot be prior art under §103. Therefore, the disclosure of Saccani *et al.* is irrelevant.

This leaves the disclosure of Toledano *et al.* However, Toledano *et al.* fails to disclose or suggest contacting an isolated nucleotide sequence comprising 5'-NGGAGANNTG-3' (SEQ ID NO:57) with a polypeptide sequence comprising RelB Rel homology domain (RHD) SEQ ID NO:62 in the presence and absence of one or more test compounds, and determining the level of specific binding of said nucleotide sequence with the SEQ ID NO:62. This negates obviousness.

In view of the above, Applicants respectfully request that the Examiner withdraw the rejection of Claim 12 under 35 U.S.C. §103(a) over Saccani *et al.* in view of Toledano *et al.*

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<sup>10</sup> Office Action, page 4, first full paragraph.

<sup>11</sup> *In re Bass*, 474 F.2d 1273, 177 USPQ 178 (CCPA 1973), *OddzOn Products Inc. v. Just Toys Inc.*, 43

**CONCLUSION**

Applicants respectfully request reconsideration of the application in view of the above, which places the claims in condition for allowance. To expedite prosecution, Applicants also respectfully invite the Examiner to **call the undersigned before drafting another written communication**, if any.

The Commissioner is hereby authorized to charge payment of any fees associated with this communication or credit any overpayment to Deposit Account No. 08-1290.

Respectfully submitted,

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